UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
THIS DOCUMENT RELATES TO:	)	Dkt. No 1:13-md-2419 (RWZ)
All Suits Against the Saint Thomas Entities	)	

SAINT THOMAS ENTITIES' MASTER ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' AMENDED MASTER COMPLAINT

Defendants Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health (collectively referred to as the "Saint Thomas Entities") file this Master Answer and Affirmative Defenses to Plaintiffs' Amended Master Complaint.

I. INTRODUCTION

1. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore deny the allegations contained therein.

2. The allegations in the first two sentences of Paragraph 2 purport to characterize findings and conclusions of the United States Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), which are in writing and speak for themselves, and the Saint Thomas Entities deny all allegations inconsistent with the FDA's or CDC's findings and conclusions. The Saint Thomas Entities are without information sufficient

to admit or deny the allegations in the third sentence of Paragraph 2, and accordingly deny the same.

3. The Saint Thomas Entities admit that New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") caused, in whole or in part, the injuries about which Plaintiffs complain and that the conditions of NECC's facility led to the fungal meningitis outbreak, but deny the remaining allegations in Paragraph 3.

4. The Saint Thomas Entities admit that Defendant Liberty Industries, Inc. ("Liberty") designed, manufactured, and installed the cleanrooms used to compound, mix, prepare, and assemble NECC's products. The Saint Thomas Entities are without information sufficient to admit or deny the remaining allegations in Paragraph 4, and accordingly deny the same.

5. The Saint Thomas Entities admit that Defendant UniFirst Corporation ("UniFirst") was hired by NECC to clean the NECC and Ameridose clean rooms, including the clean rooms where NECC's products were manufactured. The Saint Thomas Entities are without information sufficient to admit or deny the remaining allegations in Paragraph 5, and accordingly deny the same.

6. The Saint Thomas Entities admit that Plaintiffs' claims arise from the injection of medication into patients at various clinics and health care facilities. The Saint Thomas Entities are without information sufficient to admit or deny the remaining allegations in Paragraph 6, and accordingly deny the same.

7. This paragraph does not contain allegations against the Saint Thomas Entities. To the extent a response is required, denied.

8. This paragraph does not contain allegations against the Saint Thomas Entities. To the extent a response is required, denied.

9. This paragraph does not contain allegations against the Saint Thomas Entities. To the extent a response is required, denied.

II. JURISDICTION AND VENUE

10. The basis of this Court's jurisdiction is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that this Court has diversity jurisdiction over all lawsuits in these MDL Proceedings, denied.

11. Admitted.

12. Admitted.

13. Admitted.

14. Admitted.

15. Whether venue is proper is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that this Court is the proper venue for trial with respect to all lawsuits in these MDL Proceedings, denied.

16. The basis of this Court's jurisdiction is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that this Court has subject-matter jurisdiction over all lawsuits in these MDL Proceedings, denied.

III. PARTIES

Plaintiffs

17. Denied.

18. The allegations in Paragraph 18 are dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that all Defendants compounded, sold, distributed, or administered medication manufactured by NECC, denied.

Defendants

19. This paragraph does not contain allegations against the Saint Thomas Entities. To the extent a response is required, denied.

20. This paragraph does not contain allegations against the Saint Thomas Entities. To the extent a response is necessary, the Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

21. This paragraph does not contain allegations against the Saint Thomas Entities. To the extent a response is necessary, the Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

22. The allegation and list of facilities contained within Paragraph 22 purport to characterize the findings of the CDC, which are in writing and speak for themselves, and the Saint Thomas Entities deny all allegations inconsistent with or unsupported by the CDC's findings.

23. Denied.

IV. FACTUAL BACKGROUND

A. The Conigliaro Family Businesses.

1. Conigliaro Industries' Recycling Plant.

24. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

25. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

26. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

27. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

28. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

2. Gregory Conigliaro, Barry Cadden, and Douglas Conigliaro founded NECC.

29. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

30. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

31. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

32. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

33. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

34. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

3. Medical Sales Management.

35. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

36. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

4. Ameridose.

37. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

38. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

39. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

40. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

5. Alaunus Pharmaceutical.

41. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

42. No response is required to paragraph 42.

B. Background on Compounding Pharmacies.

43. Denied.

44. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

45. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

46. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

47. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

C. The Risks of Pharmacy Compounding.

48. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

49. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

50. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

51. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

52. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

53. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

54. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

55. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

D. Meningitis.

56. The allegations in Paragraph 56 contain matters of medical expertise, and accordingly are denied.

57. The allegations in Paragraph 57 contain matters of medical expertise, and accordingly are denied.

58. The allegations in Paragraph 58 contain matters of medical expertise, and accordingly are denied.

59. The allegations in Paragraph 59 contain matters of medical expertise, and accordingly are denied.

E. The Outbreak and Its Aftermath.

60. The Saint Thomas Entities admit based on information and belief that on or about September 21, 2012, the referenced communication occurred.

61. The Saint Thomas Entities admit based on information and belief that on or about September 24, 2012, the referenced communication occurred. The Saint Thomas Entities are

without information sufficient to admit or deny the remaining allegations in Paragraph 61, and accordingly deny the same.

62. The Saint Thomas Entities admit based on information and belief that the Tennessee Department of Health identified nine cases of fungal meningitis following injection of methylprednisolone acetate ("MPA"), but lack knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations asserted in Paragraph 62, and therefore, deny the allegations contained therein.

F. FDA and MDPH Begin Investigating NECC.

63. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

64. The Saint Thomas Entities admit that NECC recalled three lots of preservative-free MPA on or around September 26, 2012, but lack knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations asserted in Paragraph 64, and therefore, deny the allegations contained therein.

65. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

66. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

67. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

68. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

69. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

G. NECC Surrenders Its Pharmacy License and Recalls All of Its Products.

70. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

71. Admitted based on information and belief.

72. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

73. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

H. FDA and Massachusetts Board of Pharmacy's Findings.

74. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

75. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

I. MDPH's Preliminary Findings.

76. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 76 are inconsistent with the referenced findings, denied.

77. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 77 are inconsistent with the referenced findings, denied.

78. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 78 are inconsistent with the referenced findings, denied.

79. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 79 are inconsistent with the referenced findings, denied.

80. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 80 are inconsistent with the referenced findings, denied.

81. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 81 are inconsistent with the referenced findings, denied.

82. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 82 are inconsistent with the referenced findings, denied.

83. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 83 are inconsistent with the referenced findings, denied.

84. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 84 are inconsistent with the referenced findings, denied.

85. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 85 are inconsistent with the referenced findings, denied.

86. Admit that a true and accurate copy of the MDPH report is attached to the Master Complaint as Exhibit A. To the extent the allegations in the Paragraph 86 are inconsistent with the referenced findings, denied.

J. FDA's Initial Findings and Form 483 Report.

87. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 87 are inconsistent with the referenced findings, denied.

88. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 88 are inconsistent with the referenced findings, denied.

89. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 89 are inconsistent with the referenced findings, denied.

90. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 90 are inconsistent with the referenced findings, denied.

91. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 91 are inconsistent with the referenced findings, denied.

92. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 92 are inconsistent with the referenced findings, denied.

93. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 93 are inconsistent with the referenced findings, denied.

94. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 94 are inconsistent with the referenced findings, denied.

95. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 95 are inconsistent with the referenced findings, denied.

96. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 96 are inconsistent with the referenced findings, denied.

97. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 97 are inconsistent with the referenced findings, denied.

98. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 98 are inconsistent with the referenced findings, denied.

99. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 99 are inconsistent with the referenced findings, denied.

100. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit B. To the extent the allegations in the Paragraph 100 are inconsistent with the referenced findings, denied.

K. The Investigation Grows, Covering Other Drugs and Related Corporate Entities.

1. MDPH Shuts Down Ameridose and Suspends Insiders' Pharmacy Licenses.

101. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

2. FDA Confirms Other NECC Products Are Contaminated.

102. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

103. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

3. Board of Pharmacy Revokes Cadden, Chin and Conigliaro Pharmacy Licenses.

104. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

L. FDA and MDPH Investigate Ameridose and Alaunus Pharmaceuticals.

105. The Saint Thomas Entities admit the first sentence of Paragraph 106 based on information and belief. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the remaining information asserted, and therefore, deny the allegations contained therein.

106. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

107. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

108. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

1. FDA Confirms Ameridose's Products Are Contaminated.

109. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 109 are inconsistent with the referenced findings, denied.

110. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 110 are inconsistent with the referenced findings, denied.

111. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 111 are inconsistent with the referenced findings, denied.

112. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 112 are inconsistent with the referenced findings, denied.

113. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 113 are inconsistent with the referenced findings, denied.

114. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 114 are inconsistent with the referenced findings, denied.

115. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 115 are inconsistent with the referenced findings, denied.

116. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 116 are inconsistent with the referenced findings, denied.

117. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 117 are inconsistent with the referenced findings, denied.

118. Admit that a true and accurate copy of the FDA report is attached to the Master Complaint as Exhibit C. To the extent the allegations in the Paragraph 118 are inconsistent with the referenced findings, denied.

M. Criminal and Congressional Investigations.

119. The Saint Thomas Entities admit that the allegations in the first sentence of Paragraph 119 are correct based on information and belief. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations asserted in Paragraph 119, and therefore, deny the allegations contained therein.

120. The Saint Thomas Entities admit that the U.S. House of Representatives Energy and Commerce Committee has or is investigating the fungal meningitis outbreak, but lack

knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations asserted in Paragraph 120, and therefore, deny the allegations contained therein.

121. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

122. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

N. Subsequent Litigation.

123. Admitted.

O. Current Case Counts.

124. Admitted based on information and belief.

V. FACTUAL ALLEGATIONS

A. Liberty Industries, Inc.

125. Admitted.

126. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

127. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

128. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

129. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

130. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

131. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

132. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

133. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

134. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

135. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

B. UniFirst Corporation.

136. Admitted.

137. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

138. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

139. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

140. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

141. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

142. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

143. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

144. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

145. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

146. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

147. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

148. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

149. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

150. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

C. Clinics, Hospitals, and Physicians.

151. As defined in the Master Complaint, none of the Saint Thomas Entities are "Clinic Related Defendants," and all allegations related to Clinic Related Defendants are based on this definition. Whether Plaintiffs sought treatment from the Clinic Related Defendants is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that all Plaintiffs sought treatment from the Clinic Related Defendants, denied.

152. Denied.

153. Whether the Clinic Related Defendants administered NECC contaminated drugs, and/or NECC drugs suspected to be contaminated, to the Plaintiffs is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that all Clinic Related Defendants administered NECC contaminated drugs and/or NECC drugs suspected to be contaminated to the Plaintiffs, denied.

154. Whether the Clinic Related Defendants injected MPA directly into patients', including Plaintiffs', spinal canals so as to enter the central nervous system is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that all Clinic Related Defendants injected MPA directly into patients', including Plaintiffs', spinal canals so as to enter the central nervous system, denied.

155. Because this allegation concerns what a third party knew or should have known, denied.

156. Because this allegation concerns what a third party knew or should have known, denied.

157. Because this allegation concerns what a third party knew or should have known, denied.

158. Because this allegation concerns what a third party knew or should have known, denied.

159. Whether the use of NECC's drugs administered to the Plaintiffs has not been approved by the FDA is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that the use of NECC drugs administered to all Plaintiffs was not approved by the FDA, denied.

160. Because this allegation concerns what a third party knew or should have known, denied.

161. Because this allegation concerns what a third party knew or should have known, denied.

162. Because this allegation concerns what a third party knew or should have known, denied.

163. Whether NECC's unregulated drugs were used by the Clinic Related Defendants in lieu of commercially available drug products manufactured by FDA-regulated manufacturers is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that all Clinic Related Defendants used NECC's drugs in lieu of commercially available drug products manufactured by FDA-regulated manufacturers, denied.

164. This paragraph asserts a legal conclusion and is accordingly denied.

165. This paragraph asserts a legal conclusion and is accordingly denied.

166. This paragraph asserts a legal conclusion and is accordingly denied.

167. Because this allegation concerns what a third party knew or should have known, denied.

168. This paragraph asserts a legal conclusion and is accordingly denied.

169. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

170. Because this allegation concerns what a third party knew or should have known, denied.

171. Because this allegation concerns what a third party knew or should have known, denied.

172. This paragraph asserts a legal conclusion and is accordingly denied.

173. Because this allegation concerns what a third party knew or should have known, denied.

174. Because this allegation concerns what a third party knew or should have known, denied.

175. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

176. Denied.

177. This paragraph asserts a legal conclusion and is accordingly denied.

178. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

179. Because this allegation concerns what a third party knew or should have known, denied.

180. Because this allegation concerns what a third party knew or should have known, denied.

181. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

182. Because this allegation concerns what a third party knew or should have known, denied.

183. The Saint Thomas Entities admit that there are accredited compounding pharmacies throughout the United States. The Saint Thomas Entities are without information sufficient to admit or deny the remaining allegations in Paragraph 183, and accordingly deny the same.

184. Because this allegation concerns what a third party knew or should have known, denied.

185. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

186. Whether NECC produced MPA and other drugs administered to the Plaintiffs without preservatives is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege all NECC drugs administered to the Plaintiffs lacked preservatives, denied.

187. Because this allegation concerns what a third party knew or should have known, denied.

188. Because this allegation concerns what a third party knew or should have known, denied.

189. Denied.

190. Because this allegation concerns what a third party knew or should have known, denied.

191. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

192. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

193. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

194. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

195. Because this allegation concerns what a third party knew or should have known, denied.

196. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

197. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

198. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

199. Because this allegation concerns what a third party knew or should have known, denied.

200. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

201. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

202. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

203. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

204. The Saint Thomas Entities lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

205. Whether the drugs that the Clinic Related Defendants provided to Plaintiffs were contaminated with fungus, mold, and/or other contaminates is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that all drugs that the Clinic Related Defendants provided to Plaintiffs were contaminated with fungus, mold, and/or other contaminates, denied.

206. Whether the Plaintiffs were administered contaminated products by the Clinic Related Defendants is dependent on the facts and circumstances of each individual lawsuit. To the extent that Plaintiffs allege that all Plaintiffs were administered contaminated products by the Clinic Related Defendants, denied.

VI. GENERAL ALLEGATIONS

207. The Saint Thomas Entities admit on information and belief that products made by NECC and/or the Affiliated Defendants proximately caused some damages, injuries, and/or death. The Saint Thomas Entities deny the remaining allegations contained in Paragraph 207.

208. The Saint Thomas Entities admit on information and belief that products made by NECC and/or the Affiliated Defendants proximately caused some damages. The Saint Thomas Entities deny the remaining allegations contained in Paragraph 208.

209. The Saint Thomas Entities admit on information and belief that products made by NECC and/or the Affiliated Defendants proximately caused some spousal damages. The Saint Thomas Entities deny the remaining allegations contained in Paragraph 209.

210. The Saint Thomas Entities admit on information and belief that products made by NECC and/or the Affiliated Defendants proximately caused some children or parents damages. The Saint Thomas Entities deny the remaining allegations contained in Paragraph 210.

VII. CAUSES OF ACTION

COUNT I – NEGLIGENCE AND GROSS NEGLIGENCE (Against Liberty)

211. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 211 by incorporating its responses to such prior statements and allegations.

212. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

213. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

214. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

215. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

216. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

217. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 217 does not contain allegations that the Saint Thomas Entities can admit or deny.

COUNT II – NEGLIGENCE AND GROSS NEGLIGENCE
(Against UniFirst)

218. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 218 by incorporating its responses to such prior statements and allegations.

219. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied..

220. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

221. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

222. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied..

223. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

224. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

225. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 225 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT III – NEGLIGENCE AND GROSS NEGLIGENCE

(Against Clinic Related Defendants)

226. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 226 by incorporating its responses to such prior statements and allegations.

227. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

228. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

229. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

230. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

231. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

232. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

233. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

234. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

235. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

236. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

237. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

238. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

239. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

240. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

241. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

242. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 242 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT IV – VIOLATION OF STATE CONSUMER PROTECTION STATUTES
(Against Clinic Related Defendants)

243. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 243 by incorporating its responses to such prior statements and allegations.

244. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

245. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

246. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

247. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

248. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

249. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

250. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

251. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

252. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

253. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

254. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

255. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

256. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

257. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

258. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

259. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

260. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

261. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

262. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

263. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

264. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

265. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

266. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

267. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

268. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

269. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied..

270. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

271. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 271 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT V – VIOLATION OF M.G.L. c.93A
(Against Liberty)

272. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 272 by incorporating its responses to such prior statements and allegations.

273. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

274. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

275. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

276. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

277. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

278. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

279. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

280. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

281. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

282. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

283. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 283 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT VI – VIOLATION OF M.G.L. c.93A
(Against UniFirst)

284. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 284 by incorporating its responses to such prior statements and allegations.

285. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied..

286. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

287. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

288. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

289. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

290. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

291. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

292. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

293. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

294. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

295. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 295 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT VII – BATTERY
(Against Clinic Related Defendants)

296. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 296 by incorporating its responses to such prior statements and allegations.

297. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

298. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 298 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT VIII – FAILURE TO WARN
(Against Clinic Related Defendants)

299. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

300. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

301. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

302. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

303. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 303 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT IX – TENNESSEE PRODUCT LIABILITY CLAIMS
(Against Tennessee Clinic Related Defendants)

304. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

305. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

306. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, admitted.

307. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, admitted.

308. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, admitted.

309. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied admitted.

310. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, admitted.

311. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

312. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

313. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

314. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

315. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, admitted.

316. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

317. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

318. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

319. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

320. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

321. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

322. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied..

323. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

324. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

325. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

326. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

327. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

328. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 328 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT X - AGENCY
(Against the Clinic Related Defendants)

329. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 329 by incorporating its responses to such prior statements and allegations.

330. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

331. Because the allegations in Paragraphs 330 to 336 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

332. Because the allegations in Paragraphs 330 to 336 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

333. Because the allegations in Paragraphs 330 to 336 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

334. Because the allegations in Paragraphs 330 to 336 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

335. Because the allegations in Paragraphs 330 to 336 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

336. Because the allegations in Paragraphs 330 to 336 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 336 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT XI – CIVIL CONSPIRACY
(Against Clinic Related Defendants)

337. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 337 by incorporating its responses to such prior statements and allegations.

338. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

339. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

340. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

341. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

342. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

343. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

344. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

345. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

346. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

347. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

348. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

349. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

350. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

351. Because the allegations in Paragraphs 338 to 351 have been dismissed by the Court with respect to all cases in which the Saint Thomas Entities are named, no response is required. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 351 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT XII – WRONGFUL DEATH
(Against Each Defendant)

352. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 388 by incorporating its responses to such prior statements and allegations.

353. This paragraph contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

354. Denied.

355. Denied.

356. Denied.

357. Denied.

The unnumbered Paragraph following Paragraph 357 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT XIII – LOSS OF CONSORTIUM
(Against all Defendants)

358. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 358 by incorporating its responses to such prior statements and allegations.

359. Whether Plaintiffs were husband and wife or were parent and child is dependent on the facts and circumstances of each individual lawsuit. These general allegations are accordingly denied.

360. Denied.

361. Whether Plaintiffs have incurred and will incur expenses related to obtaining medical treatment and care for his or her spouse's, parent's, or child's injuries is dependent on

the facts and circumstances of each individual lawsuit. These general allegations are accordingly denied.

The unnumbered Paragraph following Paragraph 361 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT XIV – PUNITIVE DAMAGES
(Against all Defendants)

362. As this paragraph does no more than incorporate statements and allegations made in prior paragraphs, the Saint Thomas Entities hereby respond to Paragraph 362 by incorporating its responses to such prior statements and allegations.

363. Denied.

The unnumbered Paragraph following Paragraph 363 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

COUNT XI-A – CIVIL CONSPIRACY
(Against Clinic Related Defendants)

364. As this paragraph does no more than incorporate statements and allegations made in the Master Complaint, the Saint Thomas Entities hereby respond to Paragraph 364 by incorporating its responses to such prior statements and allegations.

365. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

366. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

367. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

368. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

369. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

370. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

371. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

372. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

373. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

374. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

375. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

376. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

377. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

378. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

379. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

380. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

381. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

382. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

383. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

384. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

385. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

386. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

387. Because the allegations in Paragraphs 365 to 387 have been dismissed by the Court, no response is required. This paragraph also contains no allegations against the Saint Thomas Entities. To the extent a response is required, denied.

The unnumbered Paragraph following Paragraph 387 does not contain a factual allegation that the Saint Thomas Entities can admit or deny.

VIII. PRAYER FOR RELIEF

The Saint Thomas Entities deny that Plaintiffs are entitled to the relief sought.

JURY DEMAND

The Saint Thomas Entities request a trial by jury composed of the maximum number of jurors allowed by law, on all issues so triable.

AFFIRMATIVE AND OTHER DEFENSES

1. Plaintiffs' Master Complaint fails to state a claim upon which relief can be granted against the Saint Thomas Entities. This is a "health care liability action" as defined in Tenn. Code Ann. § 29-26-101, *et seq.*, and any claims against the Saint Thomas Entities should be governed by that section. Any claims against them pursuant to any other theories of recovery and all other causes of action should be dismissed, including without limitation all claims relating to products liability law.

2. Any allegation in the Plaintiffs' Complaints not admitted or denied is hereby denied.

3. Plaintiffs are precluded from recovering damages in excess of the amounts recoverable pursuant to Sections 29-39-102 and 29-39-104 of the Tennessee Code, Annotated.

4. The Saint Thomas Entities affirmatively state that they complied with the laws and regulations applicable to them, and with industry standards.

5. The Saint Thomas Entities deny that their allegedly wrongful acts or omissions were a legal cause of the alleged injuries and specifically reserve the right to assert independent, intervening, or superseding cause as a defense. They affirmatively assert that the injuries to the Plaintiffs resulted from independent cause and did not come about, through, or as a result of any alleged wrongful act on their part.

6. The Saint Thomas entities reserve the right to amend their Answer to assert any defense or third-party complaints for indemnification not already asserted should justice so require, and to assert any claim for indemnity or contribution where such claims are currently stayed or become stayed due to court orders.

7. The Saint Thomas Entities reserve the right to challenge compliance with the notice and certificate of good faith requirements of Tenn. Code Ann. § 29-26-121 and 122 consistent with the Court's ruling on previously-filed "global" motions to dismiss related to 121 and 122.

8. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitation, repose, or other periods of limitation applicable to Plaintiffs' claims.

9. Plaintiffs' claims are barred, in whole or in part, because the Saint Thomas Entities did not breach any duty owed to Plaintiffs or proximately cause any damages alleged by Plaintiffs.

10. Plaintiffs' Master Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

11. Plaintiffs' alleged injuries and damages were, in whole or in part, the result of, and were caused by, preexisting physical, medical, or physiological conditions, for which the Saint Thomas Entities have no legal responsibility.

12. The Saint Thomas Entities affirmatively assert that the alleged injuries and damages to Plaintiffs, if any, are the consequence of independent, intervening, and superseding causes, and the acts of third persons over which and for which the Saint Thomas Entities have no control or right of control.

13. Plaintiffs' damages, if any, are barred in whole or in part as a result of their failure to mitigate their damages.

14. The Saint Thomas Entities deny, to the extent the actions alleged may have occurred, that any entity engaging in the activities alleged in the Master Complaint was acting as the agent or servant of the Saint Thomas Entities, or at the instruction of or subject to the control of the Saint Thomas Entities; thus, the Saint Thomas Entities are not liable for any acts or omissions of such third parties as a matter of law.

15. No act or omission of the Saint Thomas Entities was intentional, fraudulent, malicious, or reckless and, therefore, any award of punitive damages is barred.

16. Plaintiffs' claims for punitive damages are in violation of the Saint Thomas Entities' state and federal constitutional rights, including the Saint Thomas Entities' rights under the Due Process Clause of the Fifth and Fourteenth Amendments and the Excessive Fines Clause of the Eighth Amendment of the United States Constitution and similar provisions of the Constitution, laws, public policies, and statutes of Tennessee.

17. The Saint Thomas Entities did not hold Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC") out to the public as its agent and did not make any representations to Plaintiffs that STOPNC was an agent of any of the Saint Thomas Entities; thus the Saint Thomas Entities are not liable for any acts or omissions of STOPNC as a matter of law.

18. To the extent that Plaintiffs' claims have been settled or Plaintiffs will in the future settle with any person or entity with respect to the injuries asserted in the Master Complaint, the liability of the Saint Thomas Entities, if any, should be reduced accordingly.

19. Collateral sources, managed care discounts, and charitable and/or governmental benefits received, available, or to be received in the future reduce the Plaintiffs' alleged damages.

20. The Saint Thomas Entities are unaware at this time of any finalized settlements by any alleged joint tortfeasor. In the event any settlement has been or will be made by any alleged joint tortfeasor, the Saint Thomas Entities are entitled to a full credit, offset, pro rata reduction, or percentage reduction, based on the percentage of fault attributable to each settling party, person, or other entity herein, and the Saint Thomas Entities make known to the other parties and to the Court that they will avail itself of their rights.

21. The Saint Thomas Entities assert all defenses available under TENN. CODE ANN. § 29-26-101, *et. seq.*

22. The Saint Thomas Entities aver that they are precluded by law from making medical diagnoses, prescribing treatment, or making medical decisions and establishing a medical plan of care for the Plaintiffs. All of these actions are reserved to licensed physicians, and the Saint Thomas Entities are precluded from controlling or influencing those decisions, even if the physician is employed by the Saint Thomas Entities. *See* TENN. CODE ANN. § 63-6-204; TENN. CODE ANN. § 63-7-103(b); TENN. CODE ANN. § 68-11-205.

23. The Saint Thomas Entities affirmatively assert that to the extent it is shown through evidence obtained during the discovery process that any party or nonparty, including the Plaintiffs, caused or contributed to cause the injuries about which Plaintiffs complain, the Saint Thomas Entities intend to rely upon the doctrine of comparative fault for the apportionment of damages, if any are awarded in this case.

24. The Saint Thomas Entities reserve the right to amend this Master Answer and add further and additional defenses as investigation and discovery in this action proceeds. The Saint Thomas Entities also reserve the right to rely upon any affirmative defenses pleaded by other Defendants in this matter.

The following affirmative defenses shall apply only if the Saint Thomas Entities are somehow responsible for one or more Defendants who are found, either as a matter of law or by the trier of fact, to be "sellers" pursuant to Tenn. Code Ann. § 29-28-102(7) subject to claims of product liability:

25. The Saint Thomas Entities rely on the "sealed container" doctrine as an affirmative defense to the Plaintiffs' product liability claims. MPA from NECC was received in a sealed package surrounding sealed vials, and recipients were not in a position to test or inspect the contents of the vials or otherwise discover the contamination, and thus have no liability under Tennessee's Product Liability Act.

26. The Saint Thomas Entities rely on Tenn. Code Ann. § 29-28-104 as an affirmative defense to the Plaintiffs' product liability claims. Recipients of NECC product complied with all applicable federal and state statutes and administrative regulations existing at the time the MPA was manufactured, which concern the design, inspection, testing, manufacture, labeling, warning, or instructions for use of MPA. They are therefore entitled to the rebuttable presumption that the MPA was not unreasonably dangerous.

COMPARATIVE FAULT

1. In accordance with the allegations asserted in the Master Complaint, the Saint Thomas Entities affirmatively assert that the following parties caused or contributed to cause the

injuries about which Plaintiffs complain, and accordingly should be apportioned their percentage of fault at trial:

A. New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center

2. The Saint Thomas Entities assert the doctrine of comparative fault against New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC").

3. NECC is a Massachusetts corporation with a principal place of business located at 697 Waverly Street, Framingham, Massachusetts.

4. NECC is controlled by the Conigliaro and Cadden families. Barry Cadden serves as President and Gregory Conigliaro serves as Treasurer and Secretary. Barry Cadden, Gregory Conigliaro, Carla Conigliaro, and Lisa Conigliaro Cadden comprise the entire board of directors and own 100% of its equity.

5. NECC compounded, manufactured, and dispensed the MPA received by some or all of the Plaintiffs in these MDL Proceedings.

6. NECC's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

7. NECC failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

8. NECC failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

9. NECC failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the Massachusetts Board of Pharmacy ("MBP").

10. NECC violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

11. NECC violated Tennessee pharmaceutical laws and regulations, including, but not limited to:

a. Violating TENN. CODE ANN. § 63-10-305 by:

i. Engaging in conduct prohibited or made unlawful by any of the provisions of parts 2-5 of that chapter or any other state or federal laws relating to drugs or the practice of pharmacy;

ii. Being guilty of dishonorable, immoral, unethical, or unprofessional conduct; and

iii. Failing to comply with duly promulgated rules of the Tennessee Board of Pharmacy ("TBOP");

b. Violating Tenn. Comp. R. & Regs. No. 1140-01-.08 by:

i. Failing to submit a copy of NECC's May 24, 2011 inspection report conducted by the MBP to the TBOP;

ii. Failing to maintain records of prescription orders dispensed to persons residing in Tennessee;

iii. Failing to make readily available any records of prescription orders prepared and dispensed to persons residing in Tennessee;

iv. Failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee by NECC were only dispensed after NECC received patient-specific prescriptions for each of those vials; and

v. Failing to comply with the requirements for patient counseling, patient profiling, drug regimen review, and pharmaceutical care as set forth in Tenn. Comp. R. & Regs. No. 1140-03-.01.

c. Violating Tenn. Comp. R. & Regs. No. 1140-03-.03 by failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee were only dispensed after NECC received patient-specific prescriptions for each of those vials; and

d. Violating Tenn. Comp. R. & Regs. No. 1140-07-.02 by failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee were free from contamination and safe for their intended use.

12. NECC violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

13. NECC proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

14. NECC acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

15. When the MPA left NECC's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

16. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

17. As a result, NECC is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

18. NECC proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

19. NECC proximately caused the alleged injuries and damages by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBOP that NECC was operating as a compounding pharmacy rather than a manufacturer.

20. NECC owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

21. NECC breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

22. To the extent that NECC's medicine caused the damages, injuries, and/or death about which Plaintiffs complain, NECC is responsible for its percentage of fault.

B. Ameridose, LLC

23. The Saint Thomas Entities assert the doctrine of comparative fault against Ameridose, LLC ("Ameridose").

24. Ameridose is a Massachusetts limited liability company with its principal offices located at 205 Flanders Road, Westborough, MA.

25. Ameridose's managers are Gregory Conigliaro and Barry Cadden, who are both directors and shareholders of NECC.

26. Upon information and belief, Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, and Carla Conigliaro own all of the membership interests of Ameridose.

27. Ameridose was an affiliate of NECC at all relevant times.

28. Ameridose, according to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, is a "distribution center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

29. On information and belief and upon the direction of NECC's principals, on April 11, 2011, Ameridose employee Michelle Rivers requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

30. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information

and belief, there were many other occasions where employees of Ameridose, Medical Sales Management, Inc. ("MSM"), and/or Medical Sales Management SW, Inc. ("MSMSW") would perform services for NECC at the direction of NECC's principals.

31. Between 2006 and October 2012, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names.

32. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. On information and belief, one former employee of MSM and/or MSMSW has stated: "I didn't think there was any difference [between Ameridose and NECC]."

33. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

34. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC.

35. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members.

36. Ameridose compounded, manufactured, and dispensed the MPA received by some or all of the Plaintiffs in these MDL Proceedings.

37. Ameridose's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

38. Ameridose failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

39. Ameridose failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

40. Ameridose failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the MBP.

41. Ameridose violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

42. Ameridose violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

43. Ameridose proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

44. Ameridose acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

45. When the MPA left Ameridose's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

46. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

47. As a result, Ameridose is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

48. Ameridose proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

49. Ameridose proximately caused the alleged injuries and damages by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to healthcare providers that Ameridose's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBOP that Ameridose was operating as a compounding pharmacy rather than a manufacturer.

50. Ameridose owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

51. Ameridose breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

52. To the extent that Ameridose's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Ameridose is responsible for its percentage of fault.

C. Alaunus Pharmaceutical, LLC

53. The Saint Thomas Entities assert the doctrine of comparative fault against Alaunus Pharmaceutical, LLC ("Alaunus").

54. Alaunus is a Massachusetts limited liability company with its principal offices located at 687 Waverly Street, Framingham, MA.

55. Alaunus acted as a full-service wholesaler, manufacturer, repackager, and distributor.

56. Alaunus's managers are Gregory Conigliaro and Barry Cadden.

57. Alaunus was an affiliate of NECC at all relevant times.

58. Alaunus's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

59. Alaunus failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

60. Alaunus failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

61. Alaunus failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the MBP.

62. Alaunus violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

63. Alaunus violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

64. Alaunus proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

65. Alaunus acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

66. When the MPA left Alaunus's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

67. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

68. As a result, Alaunus is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

69. Alaunus proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

70. Alaunus owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

71. Alaunus breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

72. To the extent that Alaunus's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Alaunus is responsible for its percentage of fault.

D. Barry Cadden

73. The Saint Thomas Entities assert the doctrine of comparative fault against Barry Cadden.

74. Barry Cadden is a resident of the Commonwealth of Massachusetts and resides at 13 Manchester Drive, Wrentham, MA.

75. Barry Cadden owns a 17.5% interest in NECC, and is director and President of NECC. Prior to October 2012, he served as Head Pharmacist and Director of Pharmacy at NECC.

76. Barry Cadden is a founder and Manager of Ameridose and was involved in Ameridose's day-to-day operations.

77. Barry Cadden is the Treasurer and Director of MSM and MSMSW.

78. Barry Cadden's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

79. Barry Cadden failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

80. Barry Cadden failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

81. Barry Cadden failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the MBP.

82. Barry Cadden violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

83. Barry Cadden violated Tennessee pharmaceutical laws and regulations, including, but not limited to:

a. Violating TENN. CODE ANN. § 63-10-305 by:

i. Engaging in conduct prohibited or made unlawful by any of the provisions of parts 2-5 of that chapter or any other state or federal laws relating to drugs or the practice of pharmacy;

ii. Being guilty of dishonorable, immoral, unethical, or unprofessional conduct; and

iii. Failing to comply with duly promulgated rules of the TBOP.

b. Violating Tenn. Comp. R. & Regs. No. 1140-01-.08 by:

i. Failing to submit a copy of NECC's May 24, 2011 inspection report conducted by the MBP to the TBOP;

ii. Failing to maintain records of prescription orders dispensed to persons residing in Tennessee;

iii. Failing to make readily available any records of prescription orders prepared and dispensed to persons residing in Tennessee;

iv. Failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee by NECC were only dispensed after NECC received patient-specific prescriptions for each of those vials; and

v. Failing to comply with the requirements for patient counseling, patient profiling, drug regimen review, and pharmaceutical care as set forth in Tenn. Comp. R. & Regs. No. 1140-03-.01.

c. Violating Tenn. Comp. R. & Regs. No. 1140-03-.03 by failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee were only dispensed after NECC received patient-specific prescriptions for each of those vials; and

d. Violating Tenn. Comp. R. & Regs. No. 1140-07-.02 by failing to ensure that each of the 2,520 vials of MPA dispensed in Tennessee were free from contamination and safe for their intended use.

84. Barry Cadden violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

85. Barry Cadden proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

86. Barry Cadden acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

87. When the MPA left Barry Cadden's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

88. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

89. As a result, Barry Cadden is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

90. Barry Cadden proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

91. Barry Cadden proximately caused the alleged injuries and damages by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBOP that NECC was operating as a compounding pharmacy rather than a manufacturer.

92. On January 28, 2005, in a sworn statement on his initial application for a Tennessee pharmacy license, Barry Cadden answered "No" to the following question:

> Are there any charges involving moral turpitude or violation of pharmacy, or any other laws pending against you? Explain such charges or violation in detail; even to reporting minor infractions of pharmacy, liquor or narcotic laws [sic] regulations; include dates.

93. At that time, Barry Cadden had, at least three pending, but not public, complaints before the MBP.

94. Barry Cadden owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

95. Barry Cadden breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

96. To the extent that Barry Cadden's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Barry Cadden is responsible for his percentage of fault.

E. Lisa Conigliaro Cadden

97. The Saint Thomas Entities assert the doctrine of comparative fault against Lisa Conigliaro Cadden.

98. Lisa Conigliaro Cadden is a resident of the Commonwealth of Massachusetts and resides at 13 Manchester Drive, Wrentham, MA.

99. Lisa Conigliaro Cadden is the wife of Barry Cadden, owns a 17.5% interest in NECC, and serves as a director. Prior to October 2012, Lisa Conigliaro Cadden was a pharmacist at NECC, compounded drugs, and was involved in the day-to-day operations of NECC.

100. Lisa Conigliaro Cadden's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

101. Lisa Conigliaro Cadden failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

102. Lisa Conigliaro Cadden failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

103. Lisa Conigliaro Cadden failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the MBP.

104. Lisa Conigliaro Cadden violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

105. Lisa Conigliaro Cadden violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

106. Lisa Conigliaro Cadden proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

107. Lisa Conigliaro Cadden acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

108. When the MPA left Lisa Conigliaro Cadden's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

109. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

110. As a result, Lisa Conigliaro Cadden is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

111. Lisa Conigliaro Cadden proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

112. Lisa Conigliaro Cadden proximately caused the alleged injuries and damages by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBOP that NECC was operating as a compounding pharmacy rather than a manufacturer.

113. Lisa Conigliaro Cadden owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

114. Lisa Conigliaro Cadden breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

115. To the extent that Lisa Conigliaro Cadden's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Lisa Conigliaro Cadden is responsible for her percentage of fault.

F. Douglas Conigliaro

116. The Saint Thomas Entities assert the doctrine of comparative fault against Douglas Conigliaro.

117. Douglas Conigliaro is a resident of the State of Florida and resides at 2110 W. Fawsett Road, Winter Park, FL.

118. Douglas Conigliaro is the President and a director of MSM and MSMSW.

119. Upon information and belief, Douglas Conigliaro is involved in the day-to-day operations of NECC, Ameridose, MSM, and MSMSW.

120. Douglas Conigliaro's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

121. Douglas Conigliaro failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

122. Douglas Conigliaro failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

123. Douglas Conigliaro failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the MBP.

124. Douglas Conigliaro violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

125. Douglas Conigliaro violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

126. Douglas Conigliaro proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

127. Douglas Conigliaro acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

128. When the MPA left Douglas Conigliaro's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

129. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

130. As a result, Douglas Conigliaro is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

131. Douglas Conigliaro proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

132. Douglas Conigliaro proximately caused the alleged injuries and damages by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBOP that NECC was operating as a compounding pharmacy rather than a manufacturer.

133. Douglas Conigliaro owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

134. Douglas Conigliaro breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

135. To the extent that Douglas Conigliaro's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Douglas Conigliaro is responsible for his percentage of fault.

G. Gregory Conigliaro

136. The Saint Thomas Entities assert the doctrine of comparative fault against Gregory Conigliaro.

137. Gregory Conigliaro is a resident of the Commonwealth of Massachusetts and resides at 1 Mountain View Drive, Framingham, MA.

138. Gregory Conigliaro owns a 10% interest in NECC, and is a director and Treasurer, Secretary, and Vice President of NECC. Prior to October 2012, he provided financial advice, oversaw day-to-day operations, and regularly appeared in the NECC facility.

139. Gregory Conigliaro is the founder and a Manager of Ameridose and is involved in Ameridose's day-to-day operations.

140. Gregory Conigliaro is Secretary and Director of MSM and MSMSW.

141. Gregory Conigliaro's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

142. Gregory Conigliaro failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

143. Gregory Conigliaro failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

144. Gregory Conigliaro failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the MBP.

145. Gregory Conigliaro violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

146. Gregory Conigliaro violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

147. Gregory Conigliaro proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

148. Gregory Conigliaro acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

149. When the MPA left Gregory Conigliaro's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

150. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

151. As a result, Gregory Conigliaro is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

152. Gregory Conigliaro proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

153. Gregory Conigliaro proximately caused the alleged injuries and damages by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBOP that NECC was operating as a compounding pharmacy rather than a manufacturer.

154. Gregory Conigliaro owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

155. Gregory Conigliaro breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

156. To the extent that Gregory Conigliaro's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Gregory Conigliaro is responsible for his percentage of fault.

H. Carla Conigliaro

157. The Saint Thomas Entities assert the doctrine of comparative fault against Carla Conigliaro.

158. Carla Conigliaro is a resident of the State of Florida and resides at 2110 W. Fawsett Road, Winter Park, FL.

159. Carla Conigliaro owns a 55.0% interest in NECC and serves as a director of NECC.

160. Carla Conigliaro's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

161. Carla Conigliaro failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

162. Carla Conigliaro failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

163. Carla Conigliaro failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the MBP.

164. Carla Conigliaro violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2).

165. Carla Conigliaro violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room “tacky mats;”

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

166. Carla Conigliaro proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

167. Carla Conigliaro acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

168. When the MPA left Carla Conigliaro's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

169. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

170. As a result, Carla Conigliaro is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

171. Carla Conigliaro proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

172. Carla Conigliaro proximately caused the alleged injuries and damages by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBOP that NECC was operating as a compounding pharmacy rather than a manufacturer.

173. Carla Conigliaro owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

174. Carla Conigliaro breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

175. To the extent that Carla Conigliaro's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Douglas Conigliaro is responsible for her percentage of fault.

I. Glenn Chin

176. The Saint Thomas Entities assert the doctrine of comparative fault against Glenn Chin.

177. Glenn Chin is a resident of the Commonwealth of Massachusetts and resides at 173 Mechanic Street, Canton, MA.

178. Until October 2012, Glenn Chin was a pharmacist at NECC and compounded drugs at NECC.

179. Glenn Chin's negligent acts and omissions led to the contamination of MPA that was ultimately injected into some or all of the Plaintiffs.

180. Glenn Chin failed to adequately inspect and test the MPA prior to its distribution to ensure that it was free from contamination and safe for its intended use.

181. Glenn Chin failed to train and/or supervise the individuals responsible for compounding, inspecting, and/or testing the MPA to ensure that it was free from contamination and safe for its intended use.

182. Glenn Chin failed to comply with applicable state and federal laws, despite having received multiple warnings and inspections by the FDA and the MBP.

183. Glenn Chin violated state and federal laws, including, but not limited to:

a. Failing to comply with good manufacturing practices as required by 21 U.S.C. § 351;

b. Failing to obtain new drug approval as required by 21 U.S.C. § 355;

c. Distributing wholesale drugs or medications without a license in violation of Mass. Gen. Laws ch. 112, § 36A;

d. Failing to comply with all USP guidelines as required by 247 C.M.R. 9.01(3);

e. Failing to comply with USP 797 as required by 247 C.M.R. 6.15(f);

f. Dispensing medication without a valid prescription as required by 247 C.M.R. 6.15(f);

g. Failing to report all errors relating to the preparation of medications inconsistent with USP 797 as required by 247 C.M.R. 6.15(6); and

h. Dispensing medication in a manner intended to circumvent the law in violation of 247 C.M.R. 9.01(2);

i. Falsely labeling and/or directing others to falsely label MPA as “sterile”;

j. Failing to sterilize MPA and/or directing others to take actions that resulted in MPA not being sterile;

k. Creating and/or directing others to create false cleaning and/or sterilization records.

184. Douglas Conigliaro violated USP guidelines by:

a. Failing to submit adequate samples for sterility and endotoxin testing;

b. Filing only enough vials for sterility testing and leaving the remaining medication in a bulk container until sterility results were obtained;

c. Distributing compounded medication prior to receiving the results of sterility testing;

d. Failing to properly sterilize autoclaves;

e. Failing to properly validate autoclaves prior to use;

f. Failing to properly test autoclaves prior to use;

g. Failing to properly sterilize batches of MPA;

h. Failing to ensure sterility and cleanliness of the clean room used to manufacture MPA;

i. Manufacturing MPA where residual powder existed on laminar hoods creating a high risk of contamination of the drug product;

j. Failing to clean or replace the clean room "tacky mats;"

k. Compounding sterile preparations with a leaky boiler in an adjacent room creating a high risk of contamination of the drug product;

l. Placing the clean room HVAC unit near a recycling facility; and

m. Failing to maintain continuous ventilation of clean rooms.

185. Glenn Chin proximately caused the alleged injuries and damages by violating the Tennessee Products Liability Act of 1978, TENN. CODE ANN. § 29-28-101, *et seq.*

186. Glenn Chin acted as a manufacturer as defined by TENN. CODE ANN. § 29-28-102 by compounding the MPA.

187. When the MPA left Glenn Chin's control, it was in a defective condition as defined by TENN. CODE ANN. § 29-28-102 because it was contaminated and unsafe for injection into patients.

188. Contamination of the MPA proximately caused all damages, injuries, and deaths alleged by Plaintiffs.

189. As a result, Glenn Chin is strictly liable for all damages, injuries, and deaths alleged by Plaintiffs.

190. Glenn Chin proximately caused the alleged damages, injuries, and deaths by negligently or recklessly breaching various express and implied warranties codified at TENN. CODE ANN. §§ 47-2-313 to -315, including the warranties of fitness for a particular purpose and merchantability.

191. Glenn Chin proximately caused the alleged injuries and damages by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to healthcare providers that NECC's manufacturing processes and facilities were in compliance with USP guidelines;

b. Manufacturing and distributing MPA to healthcare providers in bulk for general use rather than in response to individual patient-specific prescriptions; and

c. Misrepresenting to healthcare providers, the FDA, the MBP, and the TBOP that NECC was operating as a compounding pharmacy rather than a manufacturer.

192. Glenn Chin owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use.

193. Glenn Chin breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

194. To the extent that Glenn Chin's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Douglas Conigliaro is responsible for his percentage of fault.

K. GDC Properties Management, LLC

195. The Saint Thomas Entities assert the doctrine of comparative fault against GDC Properties Management, LLC ("GDC").

196. GDC is a Massachusetts limited liability company with its principal offices located at 701 Waverly Street, Framingham, MA.

197. GDC's manager is Gregory Conigliaro, who is a director and shareholder of NECC.

198. Upon information and belief, Gregory Conigliaro owns all of the membership interests in GDC.

199. GDC is an acronym for "Gregory D. Conigliaro." GDC is the owner of the real property and is responsible for maintenance and structural improvements at 685–705 Waverly Street, Framingham, MA.

200. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM, and MSMSW.

201. In an online posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC described one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state . . . rules and regulations."

202. GDC maintained a high degree of control over the premises leased by NECC.

203. GDC knew that NECC was compounding preservative-free MPA at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

204. GDC owed a duty to Plaintiffs and their health care providers to provide medication that was free from contamination and safe for its intended use. GDC further owed a duty to maintain premises that were clean, sanitary and in all ways appropriate for the compounding of sterile medications, and to immediately take actions to correct any condition that could lead to contamination, such as roof, HVAC, boiler or equipment leaks.

205. GDC breached this duty, proximately causing Plaintiffs' alleged damages, injuries, and/or death.

206. To the extent that GDC's acts and omissions caused the damages, injuries, and/or death about which Plaintiffs complain, Douglas Conigliaro is responsible for his percentage of fault.

M. Medical Sales Management, Inc.

207. The Saint Thomas Entities assert the doctrine of comparative fault against Medical Sales Management, Inc.

208. MSM is a Massachusetts corporation with a principal place of business located at 701 Waverly Street, Framingham, Massachusetts.

209. MSM provides advertising, marketing, promotion sales, and telemarketing services, and provided such services for NECC and Ameridose.

210. MSM's officers include Douglas Conigliaro as president, Barry Cadden as treasurer, and Gregory Conigliaro as secretary, all of whom are shareholders and directors of NECC. MSM's four directors consist of Gregory Conigliaro, Barry Cadden, Lisa Conigliaro

Cadden, and Douglas Conigliaro. Gregory Conigliaro, Barry Cadden, and Lisa Conigliaro Cadden are also directors and shareholders of NECC.

211. Upon information and belief, Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, and Carla Conigliaro own the equity interests in MSM.

212. MSM was an affiliate of NECC at all relevant times.

213. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of MSM would perform services for NECC at the direction of NECC's principals.

214. MSM printed materials for and marketed both NECC's and Ameridose's products, including MPA.

215. MSM shared office space owned by GDC with NECC in Framingham, Massachusetts.

216. During the summer of 2012, MSM sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012 ARL Microbiology Report concerning the testing of the vials of MPA from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the MPA compounded by NECC.

217. MSM owed a duty to Plaintiffs and their health care providers to provide truthful information regarding the safety and sterility of NECC's products and NECC's compliance with applicable state and federal law and USP guidelines.

218. MSM breached this duty, proximately causing all damages, injuries, and/or deaths alleged by Plaintiffs.

219. MSM proximately caused the alleged damages, injuries, and/or deaths by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to health care providers that NECC's products were safe and sterile;

b. Misrepresenting to health care providers that NECC's manufacturing facilities and processes complied with USP guidelines;

c. Misrepresenting to health care providers that NECC was in compliance with all state and federal laws;

d. Assisting or causing NECC to circumvent the requirement that NECC only compound and distribute medications after receiving valid patient-specific prescriptions;

e. Failing to adequately train and/or supervise John Notarianni and/or Mario Giamei in the advertising, selling, and/or distribution of NECC's medications;

f. Failing to disclose the true conditions and regulatory history of NECC and its principals.

220. To the extent that MSM's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, MSM is responsible for its percentage of fault.

N. Medical Sales Management SW, Inc.

221. The Saint Thomas Entities assert the doctrine of comparative fault against Medical Sales Management SW, Inc.

222. MSMSW is a Massachusetts corporation with a principal place of business located at 697 Waverly Street, Framingham, Massachusetts.

223. MSMSW provides advertising, marketing, promotion sales, and telemarketing services, and provided such services for NECC and Ameridose.

224. MSMSW's officers include Douglas Conigliaro as president, Barry Cadden as treasurer, and Gregory Conigliaro as secretary, all of whom are shareholders and directors of NECC. MSMSW's four directors consist of Gregory Conigliaro, Barry Cadden, Lisa Conigliaro Cadden, and Douglas Conigliaro. Gregory Conigliaro, Barry Cadden, and Lisa Conigliaro Cadden are also directors and shareholders of NECC.

225. Upon information and belief, Barry Cadden, Lisa Conigliaro Cadden, Gregory Conigliaro, and Carla Conigliaro own the equity interests in MSMSW.

226. MSMSW was an affiliate of NECC at all relevant times.

227. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalesalesmgmt.com. Upon information and belief, there were many other occasions where employees of MSMSW would perform services for NECC at the direction of NECC's principals.

228. MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA.

229. MSMSW shared office space owned by GDC with NECC in Framingham, Massachusetts.

230. During the summer of 2012, MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012 ARL Microbiology Report concerning

the testing of the vials of MPA from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the MPA compounded by NECC.

231. MSMSW owed a duty to Plaintiffs and their health care providers to provide truthful information regarding the safety and sterility of NECC's products and NECC's compliance with applicable state and federal law and USP guidelines.

232. MSMSW breached this duty, proximately causing all damages, injuries, and/or deaths alleged by Plaintiffs.

233. MSMSW proximately caused the alleged damages, injuries, and/or deaths by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to health care providers that NECC's products were safe and sterile;

b. Misrepresenting to health care providers that NECC's manufacturing facilities and processes complied with USP guidelines;

c. Misrepresenting to health care providers that NECC was in compliance with all state and federal laws;

d. Assisting or causing NECC to circumvent the requirement that NECC only compound and distribute medications after receiving valid patient-specific prescriptions; and

e. Failing to adequately train and/or supervise John Notarianni and/or Mario Giamei in the advertising, selling, and/or distribution of NECC's medications.

f. Failing to disclose the true conditions and regulatory history of NECC and its principals.

234. To the extent that MSMSW's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, MSMSW is responsible for its percentage of fault.

O. John Notarianni

235. The Saint Thomas Entities assert the doctrine of comparative fault against John Notarianni.

236. John Notarianni is a resident of the State of Rhode Island and resides at 21 Stephanie Drive, Foster, RI.

237. John Notarrianni was a salesman for MSM and/or MSMSW on behalf of NECC and Ameridose.

238. John Notarianni owed a duty to Plaintiffs and their health care providers to provide truthful information regarding the safety and sterility of NECC's products and NECC's compliance with applicable state and federal law and USP guidelines.

239. John Notarianni breached this duty, proximately causing all damages, injuries, and/or deaths alleged by Plaintiffs.

240. John Notarianni proximately caused the alleged damages, injuries, and/or deaths by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to health care providers that NECC's products were safe and sterile;

b. Misrepresenting to health care providers that NECC's manufacturing facilities and processes complied with USP guidelines; and

c. Assisting or causing NECC to circumvent the requirement that NECC only compound and distribute medications after receiving valid patient-specific prescriptions.

d. Failing to disclose the true conditions and regulatory history of NECC and its principals.

241. To the extent that John Notarianni's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, John Notarianni is responsible for his percentage of fault.

P. Mario Giamei

242. The Saint Thomas Entities assert the doctrine of comparative fault against Mario Giamei.

243. Mario Giamei is a resident of the Commonwealth of Massachusetts and resides at 86 Boston Road, Sutton, MA.

244. Mario Giamei was a salesman for MSM and/or MSMSW on behalf of NECC and Ameridose.

245. Mario Giamei owed a duty to Plaintiffs and their health care providers to provide truthful information regarding the safety and sterility of NECC's products and NECC's compliance with applicable state and federal law and USP guidelines.

246. Mario Giamei breached this duty, proximately causing all damages, injuries, and/or deaths alleged by Plaintiffs.

247. Mario Giamei proximately caused the alleged damages, injuries, and/or deaths by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Misrepresenting to health care providers that NECC's products were safe and sterile;

b. Misrepresenting to health care providers that NECC's manufacturing facilities and processes complied with USP guidelines; and

c. Assisting or causing NECC to circumvent the requirement that NECC only compound and distribute medications after receiving valid patient-specific prescriptions.

d. Failing to disclose the true conditions and regulatory history of NECC and its principals.

248. To the extent that Mario Giamei's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, Mario Giamei is responsible for his percentage of fault.

O. United States Food and Drug Administration

249. The Saint Thomas Entities assert the doctrine of comparative fault against the United States Food and Drug Administration ("FDA").

250. The FDA owed a duty to Plaintiffs and their health care providers to ensure that MPA manufactured, sold, and distributed by NECC was sterile and safe for its intended use pursuant to the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 301, *et. seq.*

251. The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

252. The FDA proximately caused the alleged injuries and damages by negligently or recklessly failing to take action against NECC even though the FDA had authority to do so, as

asserted in its October 31, 2008 letter to NECC, which was not publicly available prior to the outbreak of fungal meningitis, and only became available after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny.

253. The FDA breached its duty, proximately causing all injuries and damages alleged by Plaintiffs.

254. The FDA proximately caused the alleged injuries and damages by negligently or recklessly failing to make publicly available all complaints, inspection reports, and information gathered during its serial investigations of NECC, described herein.

255. The FDA failed to notify the Tennessee Board of Pharmacy ("TBOP") and other state pharmacy boards of the potential threat to public health caused by NECC's non-public track record of regulatory non-compliance with state and federal law, and unsatisfactory results from on-site surveys.

256. To and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC, the only piece of information readily available to the public regarding NECC's history with regulatory agencies was the FDA's 2006 Warning Letter to NECC.

257. However, the Warning Letter does not mention any problems with MPA or any other steroids compounded by NECC, and it does not mention any reports of problems with the sterility of any medications compounded at NECC.

258. No other information regarding NECC's history with the FDA was readily and publicly available up to and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC.

259. On December 4, 2006, the FDA failed to issue a Public Health Alert to health care providers, warning them of the problems at NECC identified in the Warning Letter issued the same day.

260. To and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC, the FDA, MBP, and NECC were aware of the serious nature and extent of the repeated problems at NECC.

261. Based on information and belief, STOPNC was unaware of the serious nature and extent of NECC's problems.

262. The FDA proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after becoming aware of NECC's failure to comply with applicable state and federal laws and manufacturing guidelines, including, but not limited to, the following incidents, which were not publicly reported prior to the outbreak of fungal meningitis, and only became public after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny:

a. In April 2002, after receiving two MedWatch reports of adverse events following injections of betamethasone compounded by NECC, the FDA inspected NECC and observed problems with sterility.

b. In July 2002, after receiving three additional MedWatch reports of two patients developing bacterial meningitis at a New York hospital following injections of MPA compounded by NECC, FDA investigators determined that NECC's sterility testing procedures were not in compliance with USP guidelines for sample size in relation to lot quantities, and the FDA testing found contamination in four of the 14 vials tested.

c. In August 2002, after receiving a report that patients developed meningitis following epidural steroid injections of MPA compounded by NECC, the FDA found bacterial contamination in five of the 16 vials tested and concluded that NECC had sterility and potency issues with MPA and betamethasone.

d. On February 5, 2003, during a joint meeting with the MBP to review NECC's inspection history and ostensibly to formulate a joint state-federal strategy for achieving safe compounding practices at the company, the FDA emphasized to the MBP the serious threat to public health posed by NECC's sterile compounding practices absent improvement.

e. Following the meeting, the FDA's own investigators recommended that NECC be enjoined from compounding medication for failing to comply with good manufacturing practices in the event that the MBP failed to take action against NECC.

f. On April 27, 2004, the FDA and the MBP conducted a joint inspection of NECC after receiving two new complaints against NECC:

i. First, a Wisconsin pharmacist reported that NECC's representative told the pharmacist that NECC needed a prescription for extra strength triple anesthetic cream, but the representative stated that the pharmacist could use the name of a staff member. NECC's representative also stated that another healthcare provider used a nurse's name.

ii. Second, an Iowa pharmacist reported that NECC was advertising compounded prescription products for use by multiple patients with a single prescription.

g. On September 23, 2004, the FDA and the MBP conducted a joint inspection of NECC after receiving a complaint that NECC was compounding Trypan Blue Dye for use as a capillary stain during ophthalmic procedures, which was not an approved use.

i. During the inspection, Barry Cadden, an owner, and the pharmacist in charge at NECC, told investigators that NECC did not compound Trypan Blue until they received a prescription.

ii. But soon thereafter, investigators discovered a drawer with 189 vials of Trypan Blue, with no corresponding prescriptions.

h. In November 2004, Barry Cadden admitted in a letter to the MBP, which was later shared with the FDA, that NECC had filled prescriptions for Trypan Blue using invalid patient names.

i. In May 2011, the FDA's district office in Denver, Colorado notified the New England District Office of the FDA that NECC had violated a Cease and Desist Letter issued by the Colorado Board of Pharmacy that prohibited NECC from distributing drugs in Colorado without receiving patient-specific prescriptions.

j. The FDA took no meaningful, substantive action.

263. The FDA proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after issuing a Warning Letter to NECC on December 4, 2006, detailing numerous problems at NECC, including:

a. Compounding drugs without patient-specific prescriptions;

b. Compounding copies of commercially-available drugs;

c. Selling misbranded compounded drugs; and

d. Failing to correct problems with storage and sterility.

264. On January 5, 2007, NECC responded to the FDA's Warning Letter, but NECC's response letter was not publicly available up to and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC.

265. On October 31, 2008, the FDA replied to NECC's response in a third letter that was not publicly available up to and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC.

266. The FDA, based on available information, failed to perform the follow-up inspection promised in its October 31, 2008 letter.

267. The FDA failed to take any readily apparent action against NECC after sending the December 4, 2006 Warning Letter, even though the Warning Letter threatened "additional regulatory action without further notice."

268. The FDA proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC even though the FDA knew that NECC had violated the FDA's Compliance Policy Guidance on Pharmacy Compounding in, at least, the following ways:

a. Compounding drugs in anticipation of receiving prescriptions (as evidenced by multiple complaints from state pharmacy boards as well as the FDA's own inspections);

b. Using commercial scale compounding equipment for compounding drug products (e.g., ExactaMix EM2400 compounders);

c. Compounding drug products that were commercially available in the marketplace or that were essentially copies of commercially available FDA-approved

drug products (as evidenced by a 2004 patent infringement lawsuit filed by Dusa Pharmaceuticals against NECC for copying a commercially available FDA-approved drug manufactured by Dusa Pharmaceuticals); and

d. Failing to operate in conformance with applicable state law regarding the practice of pharmacy (as evidenced by multiple complaints from state pharmacy boards as well as the FDA's own inspections).

269. The FDA proximately caused the alleged injuries and damages by negligently or recklessly failing to adequately inspect ARL BioPharma, Inc. ("ARL") pursuant to the authority granted by 21 U.S.C. § 360(h), prior to November 8, 2012, when the FDA discovered multiple violations related to the testing of NECC medications including:

a. Failing to comply with USP 71 when performing sterility and/or fungal testing on NECC products by:

i. Failing to maintain adequate documentation demonstrating the performance of Method Suitability Testing on all new NECC products tested; and

ii. Failing to ensure that NECC submitted the required number of vials for testing.

b. Failing to comply with USP 85 in performing endotoxin testing by:

i. Failing to calculate the Maximum Valid Dilution using the formula in USP 85; and

ii. Failing to ensure that each client provided the dosing information required to calculate the Maximum Valid Dilution using the formula in USP 85.

c. Failing to maintain documentation demonstrating validation of all analytical methods for testing the potency of NECC's products; and

d. Failing to conduct further investigation following 13 endotoxin testing failures that occurred between October 2010 and October 2012.

270. To the extent that the FDA's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, the FDA is responsible for its percentage of fault.

P. Massachusetts Board of Registration in Pharmacy

271. The Saint Thomas Entities assert the doctrine of comparative fault against the Massachusetts Board of Registration in Pharmacy ("MBP").

272. The MBP owed a duty to Plaintiffs and their health care providers to ensure that NECC compounded medication free from contamination and operated in compliance with applicable Massachusetts pharmaceutical laws pursuant to Mass. Gen. Laws ch. 112, § 32.

273. The MBP breached this duty, proximately causing all damages, injuries, and deaths alleged by Plaintiffs.

274. The MBP proximately caused the alleged injuries and damages by negligently or recklessly failing to make publicly available all complaints, inspection reports, and information gathered during investigations regarding NECC, described herein.

275. On information and belief, the MBP failed to notify the TBOP and other state pharmacy boards of the potential threat to public health caused by NECC's non-public track record of regulatory non-compliance with state and federal law, and unsatisfactory results from on-site surveys.

276. To and including the time when STOPNC ordered and received shipment of the contaminated MPA from NECC, the MBP, the FDA, and NECC were aware of the serious nature and extent of the repeated problems at NECC.

277. None of the information regarding the MBP's serial inspections and investigations of NECC was readily and publicly available up to and including the time when STOPNC ordered and received shipment of the contaminated MPA.

278. On information and belief, STOPNC was unaware of the serious nature and extent of NECC's problems.

279. The MBP proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC after becoming aware of NECC's failure to comply with applicable state and federal laws and manufacturing guidelines, including, but not limited to, the following incidents, which were not publicly reported prior to the outbreak of fungal meningitis, and only became public after the state and federal agencies with the responsibility to oversee NECC were subjected to appropriate scrutiny:

a. In 1999, Barry Cadden violated MBP regulations by providing a practitioner with blank prescription pads referring to NECC.

b. In 2001, the Idaho Board of Pharmacy reported to the MBP that NECC was soliciting business for drug products which should have been discontinued by the manufacturer.

c. In 2002, the Nevada Board of Pharmacy reported to the MBP that NECC was selling non FDA-approved products to physicians in Nevada.

d. Between 2002 and 2004, the MBP received complaints from the boards of pharmacy for Texas, South Dakota, Iowa, and Wisconsin, reporting that NECC was illegally soliciting out-of-state prescriptions for office use.

e. In March 2002, the MBP and the FDA conducted a joint inspection of NECC following the FDA's receipt of two MedWatch reports of adverse events resulting from injections of betamethasone compounded at NECC.

i. During the joint investigation, the MBP apparently failed to inform the FDA of the MBP's past inspections of NECC.

ii. The MBP also apparently failed to disclose positive endotoxin testing results for the implicated lot of betamethasone to the FDA.

iii. The FDA expressed serious concerns regarding the sterility of NECC's betamethasone compounding and NECC's recordkeeping in the 483 report issued by the FDA following the investigation.

f. In July 2002, after receiving three additional MedWatch reports of two patients developing bacterial meningitis at a New York hospital following injections of MPA compounded at NECC, FDA investigators determined that NECC's sterility testing procedures were not in compliance with USP guidelines for sample size in relation to lot quantities, and FDA testing found contamination in four of the 14 vials tested.

g. In August 2002, after receiving a report that patients developed meningitis following epidural steroid injections of MPA compounded by NECC, the FDA found bacterial contamination in five of the 16 vials tested and concluded that NECC had sterility and potency issues with MPA and betamethasone.

h. However, on February 5, 2003, during a meeting between the FDA and the MBP, the MBP agreed that it, rather than the FDA, would either require compliance from NECC or take action against NECC.

i. At the February 5, 2003 meeting, the FDA recommended that NECC be prohibited from manufacturing until it demonstrated the ability to make product reproducibly and dependably.

ii. Also at the February 5, 2003 meeting, the FDA warned of the potential for serious public health consequences if NECC's sterile compounding practices were not improved.

iii. The MBP did not discernibly respond to these recommendations and warnings.

i. After the February 5, 2003 meeting, the MBP delayed more than a year before proposing a consent agreement to NECC on September 21, 2004.

i. However, NECC refused to enter into the agreement. The MBP failed to proceed to a formal hearing as provided for in the consent agreement in the event of a refusal by NECC to accept the proposal.

ii. On April 27, 2004, the FDA and the MBP conducted another joint inspection of NECC after receiving two new complaints against NECC:

1. First, a Wisconsin pharmacist reported that NECC's representative told the pharmacist that NECC needed a prescription for extra strength triple anesthetic cream, but the representative stated that the pharmacist could use the name of a staff member.

The representative also stated that another healthcare provider used a nurse's name.

2. Second, an Iowa pharmacist reported that NECC was advertising compounded prescription products for use by multiple patients with a single prescription.

j. On September 23, 2004, the FDA and the MBP conducted a joint inspection of NECC after receiving a complaint that NECC was compounding Trypan Blue Dye for use as a capillary stain during ophthalmic procedures, which was not an approved use.

i. During the inspection, Barry Cadden told investigators that NECC did not compound Trypan Blue until they received a prescription.

ii. But soon thereafter, investigators discovered a drawer with 189 vials of Trypan Blue, with no corresponding prescriptions.

iii. In November 2004, Barry Cadden admitted to the MBP that NECC had filled prescriptions for Trypan Blue using invalid patient names.

k. On January 30, 2006, the MBP received an initial audit from Pharmacy Support, inc., an independent evaluator, reporting that NECC was not in substantial compliance with USP 795 or USP 797. The audit noted the following deficiencies:

i. Documentation practices were inadequate;

ii. Written procedures were admittedly not followed routinely;

iii. Procedures were not in strict accordance with USP standards;

iv. End product testing was often performed on stock solutions and not the end product as required; and

v. Validation of sterilization cycles and media fills was inadequate.

l. On April 7, 2006, the MBP received Pharmacy Support, Inc.'s final report, which concluded that NECC needed to redesign Clean Room 1 in order to achieve compliance with USP 795 and USP 797.

m. On December 4, 2006, the FDA issued a Warning Letter to NECC detailing numerous problems at NECC including:

i. Compounding drugs without patient-specific prescriptions;

ii. Compounding copies of commercially-available drugs;

iii. Selling misbranded compounded drugs; and

iv. Having problems with storage and sterility.

280. The MBP proximately caused the alleged injuries and damages by negligently or recklessly failing to discipline or take action against NECC in February 2003 after issuing formal complaints against NECC identifying serious problems including:

a. Failing to follow sterility guidelines and procedures;

b. Failing to follow record-keeping requirements;

c. Failing to follow batch record-keeping requirements;

d. Failing to provide certificates of analysis;

e. Failing to provide proof of sterility testing;

f. Failing to provide endotoxin test results;

g. Failing to provide batch numbers; and

h. Failing to provide prescriptions upon request.

281. However, the MBP failed to pursue any disciplinary action against NECC that would actually correct these problems even though the MBP investigator who performed a follow-up inspection in late February 2003 recommended a formal reprimand.

282. The MBP proximately caused the alleged injuries and damages by negligently or recklessly failing to shut down, or even inspect NECC, after receiving notice from the Colorado Board of Pharmacy on July 26, 2012 that NECC had violated a Cease and Desist Order issued by the Colorado Board of Pharmacy prohibiting NECC from selling medications in Colorado prior to receiving patient-specific prescriptions.

283. If the MBP had promptly acted on the July 26, 2012 report, it would have discovered the dismal sterility conditions at NECC and required a recall of all NECC medications before some or all Plaintiffs received injections in August 2012.

284. In November 2012, James Coffey, the Director of the MBP, was terminated for failing to investigate NECC following receipt of the report from the State of Colorado, and for covering up the MBP's receipt of the July 26, 2012 report from the Colorado Board of Pharmacy.

285. To the extent that the MBP's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, the MBP is responsible for its percentage of fault.

Q. Tennessee Board of Pharmacy

286. The Saint Thomas Entities assert the doctrine of comparative fault against the Tennessee Board of Pharmacy ("TBOP").

287. Plaintiffs have alleged that the Saint Thomas Entities and/or their alleged agents had a duty to inspect NECC's facilities prior to purchasing medications, had a duty to determine NECC's history of recalling medications, had a duty to investigate NECC's history with the FDA and MBP, and otherwise had a duty to perform due diligence in investigating and selecting NECC.

288. The TBOP had the explicit legal authority to inspect NECC, which was doing business in Tennessee as a licensee of the TBOP.

289. The Saint Thomas Entities assert the doctrine of comparative fault against the TBOP in order to avoid waiver of the issue under Rule 8.03 of the Tennessee Rules of Civil Procedure and the Tennessee Supreme Court's decision in *George v. Alexander,* 931 S.W.2d 517, 520–21 (Tenn. 1996).

290. To the extent it is established that the TBOP breached its duty by: failing to timely investigate and bring charges against NECC for the violations outlined herein; failing to inquire of the MBP regarding actions against NECC; or failing to inspect NECC's facility, the Saint Thomas Entities assert fault against the TBOP.

291. Plaintiffs have alleged that the Saint Thomas Entities and/or their alleged agents, as private health care providers, had the duty to fully investigate and inspect NECC before doing business with it in Tennessee. Based on these allegations, the Saint Thomas Entities plead the fault of the TBOP and assert that any findings of fault against the Saint Thomas Entities and/or their alleged agents for failure to act reasonably in choosing NECC be compared against any fault found on the part of the TBOP for failing to comply with its duty to reasonably evaluate and license NECC.

R. Tennessee Department of Health

292. The Saint Thomas Entities assert the doctrine of comparative fault against the Tennessee Department of Health ("TDH").

293. Based on specific allegations in Plainitffs' Complaints, the Saint Thomas Entities are required to assert comparative fault against the TDH for any claims arising from an alleged failure to notify Plaintiffs of their potential exposure to contaminated MPA prior to any respective hospitalization.

294. The Saint Thomas Entities assert the doctrine of comparative fault against the TDH in order to avoid waiver of the issue under Rule 8.03 of the Tennessee Rules of Civil Procedure and the Tennessee Supreme Court's decision in *George v. Alexander,* 931 S.W.2d 517, 520–21 (Tenn. 1996).

295. The Saint Thomas Entities allege that the TDH's actions were a cause-in-fact or a substantial factor in causing the Plaintiffs alleged injuries arising from the alleged failure to warn.

296. On information and belief, from the time STOPNC, the Saint Thomas Entities' alleged agent, learned of potential exposure, it worked closely with the TDH to respond appropriately, particularly in the first days of the outbreak. On information and belief, STOPNC relied on the TDH for advice on contacting patients and responded to the outbreak both consistent with and in tandem with the TDH, and within the acceptable standards of professional practice.

297. On information and belief, STOPNC promptly complied with all instructions from the TDH and CDC regarding contacting patients, including an initial directive from the TDH not to mention meningitis.

298. STOPNC relied upon and promptly complied with all directives and guidance received from the TDH related to this fungal meningitis outbreak.

299. If it is established that the TDH did not recommend appropriate notification of patients, the Saint Thomas Entities are constrained to assert comparative fault against the TDH.

S. Liberty Industries, Inc.

300. The Saint Thomas Entities assert the doctrine of comparative fault against Liberty Industries, Inc. ("Liberty").

301. Liberty designed, manufactured, and installed the cleanrooms used to compound, mix, prepare, and assemble NECC's products. Plaintiffs allege that Liberty's cleanrooms contained defects that made them unsuitable for their intended use and vulnerable to the manufacture of contaminated products. Without Liberty, there would have been no clean rooms for NECC to compound medicine in, and that without the alleged defects in Liberty's clean rooms, the contamination may well have been avoided.

302. To the extent that the Liberty's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, Liberty is responsible for its percentage of fault.

T. UniFirst Corporation, a/d/b/a UniClean Cleanroom Services.

303. The Saint Thomas Entities assert the doctrine of comparative fault against UniFirst Corporation, a/d/b/a UniClean Cleanroom Services ("UniFirst").

304. UniFirst was hired by NECC to clean the NECC and Ameridose clean rooms, including the clean rooms where the contaminated products were manufactured.

305. UniFirst advertises that its services will "improve the safety and cleanliness" of a business facility.

306. UniFirst contracted with NECC to, and did, provide cleaning services to NECC and/or Ameridose, including with respect to the clean rooms.

307. NECC's internal records report numerous instances of reported mold and bacterial contamination in the months leading up to the outbreak.

308. Plaintiffs allege that UniFirst failed to provide adequate cleaning services that would have prevented contamination of the drugs made in NECC's clean rooms.

309. To the extent that UniFirst's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, UniFirst is responsible for its percentage of fault.

U. ARL BioPharma, Inc.

310. The Saint Thomas Entities assert the doctrine of comparative fault against ARL BioPharma, Inc. ("ARL").

311. ARL is an Oklahoma corporation with a principal place of business located at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma, 73104.

312. ARL owed a duty to Plaintiffs and their health care providers to properly test medications submitted by NECC that would eventually be administered to Plaintiffs by their health care providers.

313. ARL breached this duty, proximately causing all damages, injuries, and/or deaths alleged by Plaintiffs.

314. ARL proximately caused the alleged damages, injuries, and/or deaths by negligently or recklessly committing various acts or omissions, including, but not limited to:

a. Failing to discover contamination in the three contaminated lots of MPA from NECC, lots 05212012@68, 06292012@26, and 08102012@51;

b. Failing to comply with guidelines governing the testing of NECC's medications, including, but not limited to:

i. Failing to comply with USP 71 when performing sterility and/or fungal testing on NECC products by:

1. Failing to maintain adequate documentation demonstrating the performance of Method Suitability Testing on all new NECC products tested; and

2. Failing to ensure that NECC submitted the required number of vials for testing.

ii. Failing to comply with USP 85 when performing endotoxin testing by:

1. Failing to calculate the Maximum Valid Dilution using the formula in USP 85; and

2. Failing to ensure that each client provided the dosing information required to calculate the Maximum Valid Dilution using the formula in USP 85.

iii. Failing to maintain documentation demonstrating validation of all analytical methods for testing the potency of NECC's products; and

iv. Failing to conduct further investigation following 13 endotoxin testing failures that occurred between October 2010 and October 2012.

315. To the extent that ARL's acts and omissions caused the damages, injuries, and/or deaths about which Plaintiffs complain, ARL is responsible for its percentage of fault.

V. Additional Parties Known and Unknown

316. The Saint Thomas Entities further rely upon the doctrine of comparative fault, to the extent that the discovery or proof in these cases should reveal that the direct and proximate cause, or a contributing cause, of any damages, injuries, or deaths of Plaintiffs was any act or omission by any person or entity which is a party to this litigation, a party to the *In re New England Compounding Pharmacy, Inc.* Bankruptcy Proceedings before the United States Bankruptcy Court for the District of Massachusetts, Case No. 12-19882, by way of initiating adversary proceedings or filing Proofs of Claim, as well as any person or entity not a party to this litigation. The Saint Thomas Entities reserve the right to amend their answer to assert the specific conduct of parties to this action or other persons, as the facts become more fully known through discovery.

WHEREFORE, the Saint Thomas Entities pray that:

(1) Plaintiffs take nothing by reason of the Master Complaint;

(2) that a Judgment against Plaintiffs and in favor of the Saint Thomas Entities be entered;

(3) The Saint Thomas Entities be awarded their costs and expenses; and

(4) this Court award the Saint Thomas Entities any other and general or specific relief as this Court may deem just and proper.

Dated: September 30, 2014

By their attorneys,

/s/ Sarah P. Kelly

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*Appearing *Pro Hac Vice*

CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 1st day of October, 2014

/s/ Sarah P. Kelly
Sarah P. Kelly

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